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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/538,223	06/29/2005	Heinz Schneider	09600-00031-US	9409

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EXAMINER
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ALONIS, MELENIE LEE

ART UNIT	PAPER NUMBER
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1655

DATE MAILED: 04/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/538,223	SCHNEIDER, HEINZ	
	<b>Examiner</b>	<b>Art Unit</b>	
	Melenie Alonis	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 3-12 and 15-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3-12 and 15-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

### **DETAILED ACTION**

Claims 3-12 and 15-21 are presented for examination on the merits.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3-12 and 15-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 10,12, and 16 are rendered vague and indefinite by the phrase "gastrointestinally administering a composition" (see e.g. claim 10) and the phrase "for gastrointestinal administration" (see. e.g. claim 16). It is unclear to whom or what the composition is being administered- e.g., a human, an animal, a removed section of the gastrointestinal tract?

Claims 10 and 15 are rendered vague and indefinite by the phrase "for the support of surgical patients". It is unclear what is meant by the term "support"-physical support, mental support, etc.

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under USC 112, second paragraph for the reasons set forth above.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3-12 and 15-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Inanami et al. (Free Radic Res), Schneider et al. (US 6,656,608) and Jerkic et al. (Nephro Dial Trans), and further in view of Wu et al. (J. Nutr.).

A composition and a method of using the composition comprising a green tea extract and at least one NO donor which is a substrate of NO synthetase, and/or one precursor of this NO donor is claimed. Dependent claims further disclose that the NO donor of the instantly claimed invention is selected from a group which includes arginine. The green tea extract of the instantly claimed invention includes theanine and polyphenols derived from catechin derivatives. The catechin derivatives are further disclosed to be selected from a group which includes (-) -catechin. Dependent claims include the composition further comprising glycine.

Inanami et al. beneficially teach the protective effects of the green tea polyphenol (-) catechin against damage in the brain caused by ischemia in gerbils. Inanami et al. further teach that the compound is intended to be orally (gastrointestinally) administered prior to a reperfusion event (surgery)- see entire document including abstract and methods. Please note that theanine is one of the predominant amino acids present in green tea, and would intrinsically be present in an extract of green tea. Inanami et al. do not expressly teach that the composition further comprises glycine or at least one NO donor which is a substrate of NO synthetase.

Schneider et al. beneficially teach that glycine is useful in protecting against damage caused by ischemia reperfusion. Schneider et al. further beneficially teach that a composition comprising glycine is intended to be administered orally (see e.g. col 5 line 66-col 6 line 2). Schneider et al. also further beneficially teach that the composition is intended as a pre-operative treatment (see e.g. col. 6 lines 21-23). Schneider et al. also disclose that the composition may additionally contain arginine (see e.g. claim 7).

Jerkic et al. beneficially teach the protective effects of L-arginine administration in rats prior to a surgical procedure which would result in reperfusion injury. Jerkic et al. further beneficially teach that L-arginine administration is through drinking water (gastrointestinal administration) prior to the surgery.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the green tea extract taught by Inanami et al. and the glycine and L-arginine taught by Schneider et al. and Jerkic et al., respectively, to obtain a composition which would be useful for treating preoperative patients to reduce the risk of post operative complications (such as the oxidative injury caused by ischemia reperfusion). Since it is well known in the art that the majority of damage resulting from ischemia reperfusion is related to oxidative stress, it would have been obvious to the skilled artisan to combine a well known antioxidant (green tea extract) with L-arginine, especially since, as evidenced by Wu et al., L-arginine is notoriously well recognized in the art to be the main precursor of nitric oxide which is a known mediator of reperfusion (see Wu et al.-e.g., page ,2628). Since it has also been shown that glycine may be useful as a treatment to protect against ischemia reperfusion (as

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disclosed by Schneider et al.), it would have been obvious to include this compound in composition which was to be used for the same purpose. The adjustment of particular conventional working conditions (e.g. administering the composition to a patient at a certain time before or after surgery) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

### ***Conclusion***

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melenie Alonis whose telephone number is (571) 272-8037. The examiner can normally be reached on M-F 7:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Melenie Alonis  
Art Unit 1655



**CHRISTOPHER R. TATE**  
**PRIMARY EXAMINER**